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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/141,017	10/26/1993	EUGENE P. GOLDBERG	4733	7268

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MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
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EXAMINER	
FISHER, ABIGAIL L	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
03/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	08/141,017	GOLDBERG ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on November 24 2008 is acknowledged. Claim 2 stands cancelled. Claims 1, 3-7 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Terminal Disclaimer

The terminal disclaimer filed on March 12 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5140016 and 5632979 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

The examiner acknowledges Applicants' argument that acknowledgement of the terminal disclaimers to US Patent No. 5140016 and 5632979 were not made. The examiner acknowledges that 5140012979 does not correspond to a US Patent No. to which a TD was filed. This number was a typo and was a combination of the two Patent No. that were not included.

Claim Objections

The objection of claim 5 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is **withdrawn** in light of Applicants' amendment filed on November 24 2008 amending the claim to recite a particular molecular weight of the hyaluronic acid.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as chondroitin sulfate and hyaluronic acid which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) 1, 6-7 is(are) directed to encompass any polypeptide or polysaccharide with a molecular weight of about 50,000 D or above, which only correspond in some undefined way to specifically instantly disclosed chemicals. None

of these polysaccharides or polypeptides meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. Specifically, a polypeptide is comprised of more than one amino acid. The instant specification provides no guidance or description as to what amino acids are envisaged as constituting parts of the polypeptide. Amino acids have a molecular weight of roughly 120. Therefore, in order to possess a molecular weight of about 50,000 about 400 or more amino acids would be required. Since there is no description of any peptides that applicants' have contemplated as being useful for the invention the genus encompasses an enormous possible combination of amino acids. The same analog would apply for polysaccharides as this is a long chain of various sugars either homogenously or heterogeneously. The specification provides insufficient written description to support the genus encompassed by the claim. **Note: MPEP 2163.**

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed **polypeptides or polysaccharides,** regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Circ. 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing “sufficiently detailed, relevant identifying characteristics,” including “functional characteristics when coupled with a known or disclosed correlation between function and structure.” Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus

because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of Applicants' amendment filed on November 24 2008 amending the claim to recite a particular molecular weight of the hyaluronic acid.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 recite above about 1,500,000. This renders the claims indefinite as it is unclear what constitutes the lower limit of the claimed molecular weight. Is the lower limit above 1,500,000 or about 1,500,000. In other words, employing the two terms (about and above) together renders the scope of the limitation indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 3, and 6-7 under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (US Patent No. 4819617) is **withdrawn** in light of Applicants' argument that Goldberg et al. does not qualify as art based on its publication date is not available for its 102(e) date.

Claims 1, 4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert (US Patent No. 4585666) in view of Schwartz et al. (US Patent No. 4589873).

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Lambert is directed to a coating for a polymer surface. The hydrophilic coating has a low coefficient of friction and can be utilized to coat medical articles(column 1, lines 8-10). Examples 1 and 2 are directed to coating a urinary catheter. The catheter is dipped in a PVP solution and then cured above a bowl filled with water. It is disclosed that he presence of water during the curing process is to help bind the hydrophilic PVP (column 2, lines 53-67). The PVP is utilized in a solution from 0.5 to 10% (column 2, lines 49-51). The molecular weight of the PVP is from 10^4 to 10^7 (column 2, lines 41-42). Other surfaces that may be coated include latex rubber (column 1, line 56).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Lambert et al. does not specify that the PVP can be dissolved in water. However, this deficiency is cured by Schwartz et al.

Schwartz et al. indicates that the hydrophilic polymer PVP is water soluble (column 1, lines 49-50).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Lambert et al. and Schwartz et al. and dissolve the PVP in water. One of ordinary skill in the art would have been motivated to utilize water as the solvent which to dissolve PVP because Schwartz et al. teach that PVP is water soluble. Additionally, since water is utilized in the curing process of Lambert et al., utilizing water as the solvent which to dissolve PVP would eliminate the step of having to remove a different solvent and one could go immediately from coating to curing.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding claim 6, applicant claims broad surgical classes. Schwartz et al. teach that the PVP solution can be utilized to coat latex rubber, such as rubber gloves.

Gloves would be utilized in every type of surgery as they are a necessary component of a surgical procedure.

Response to Arguments

Applicants argue that (1) Lambert and Schwartz have been cited in the instant inventor Goldberg patents 5080893, 5140016, etc. and since the instant application has terminal disclaimers filed and approved over these patents, the cited prior art cannot now do what it did not previously do, i.e. it cannot render the present claims obvious. Applicants argue that (2) Lambert does not disclose molecular weights of the polymer nor the use of aqueous solutions and Schwartz disclose molecular weights only up to 1,000,000 and does not disclose the use of aqueous solutions. Applicants argue that (3) neither Lambert nor Schwartz disclose coating tissue surfaces.

Applicants' arguments filed November 24 2008 have been fully considered but they are not persuasive.

Regarding Applicants' first argument, while terminal disclaimers have been filed to applicants' other applications and the respective scopes overlap they are not the same. For example, the molecular weight limitations of the instant application are broader than that of the other patents. Furthermore, each application is considered individually and arguments presented in other applications are not applicable here unless they are presented here.

Regarding applicants second argument, Lambert discloses molecular weights of polyvinylpyrrolidone of 10^4 to 10^7 (100,000 to 100,000,000). The instant claims require that the polymeric material has a molecular weight of 50,000 or above. The upper limit

for polyvinylpyrrolidone as instantly claimed is infinite. Only hyaluronic acid as instantly claimed has an upper ceiling. Therefore, the molecular weight taught by both Lambert and Schwartz for the polyvinylpyrrolidone would meet the limitation set forth in the instant claims. Schwartz teaches that polyvinylpyrrolidone is water soluble. Based on that teaching, it would have been obvious to one of ordinary skill in the art to utilize water as the solvent which to dissolve PVP because Schwartz et al. teach that PVP is water soluble. Additionally, since water is utilized in the curing process of Lambert et al., utilizing water as the solvent which to dissolve PVP would eliminate the step of having to remove a different solvent and one could go immediately from coating to curing.

Regarding applicants' third argument, as instantly claimed the surface can be a tissue **OR** surgical article **OR** both. Therefore, the teachings of Lambert of coating medical articles and gloves would be inclusive of surfaces of surgical articles.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 1 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soll et al. (US Patent No. 4486416) as evidenced by Gough (US Patent No. 4335105).

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue

during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Soll et al. is directed to protection of human and animal cells subject to exposure to trauma. It is taught that macromolecules employed in the protection of corneas prior to surgery include bovine serum albumin (a protein which is necessarily a polypeptide), human gamma globulin, hyaluronic acid, and polyvinylpyrrolidone (column 1, lines 24-31). Tables 2 and 3 show the use of chondroitin sulphate, bovine serum albumin, hyaluronic acid and polyvinylpyrrolidone were tested for their protection of corneas during implantation surgery. It is taught that solutions were made with normal saline (column 7, liens 31-42). The amount of bovine serum albumin utilized was 22%, hyaluronic acid was 10% and polyvinylpyrrolidone was 7% (column 9, lines 1-11). It is taught that the molecular weight of HEALON is greater than 1,000,000 (column 4, liens 39-41).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Soll et al. does not explicitly teach utilizing the polyvinylpyrrolidone, bovine serum albumin, or hyaluronic acid in the claimed method. However, Soll et al. do teach that

they are known in the art to be employed in the protection of corneas prior to surgery and that they do provide some degree of protection.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize bovine serum albumin or hyaluronic acid in a method of protecting corneas prior to surgery. One of ordinary skill in the art would have been motivated to utilize these polymers in a method of protecting corneas it is taught by Soll et al. that these polymers are known in the art to be utilized for protecting corneas prior to surgery. One of ordinary skill in the art would have a reasonable expectation of success as Soll et al. teach that bovine serum albumin and hyaluronic acid provide some degree of protection of corneas prior to surgery.

Regarding the molecular weight of hyaluronic acid, the instant claims recite a molecular weight greater than 50,000 but the hyaluronic acid needs to be less than 1,500,000. Soll et al. teach the molecular weight of the hyaluronic acid is greater than 1,000,000. Therefore, the molecular weight would meet the instant limitations as it includes values below 1,500,000.

Regarding the molecular weight of bovine serum albumin, as evidenced by Gough the molecular weight of bovine serum albumin is 66,000 (column 8, lines 58-59).

Regarding the claimed types of surgery, corneal surgery would broadly fall under reconstructive, prosthetic, plastic or muscle surgery.

Regarding the claimed amount of bovine serum albumin, 22% is about 15.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

It is noted that the claims have previously been rejected over Soll et al. (See Office action mailed on January 12 2006). However that rejection was overcome by the incorporation of the negative limitation excluding chondroitin sulfate, salt, complex or mixture thereof in the reply filed on January 10 2006. However, the instant rejection utilizes the teaching of the other polymers taught by Soll et al. as coating materials.

Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soll et al. as evidenced by Gough and in view of Lambert.

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and

the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Specifically claimed polymer is polyvinylpyrrolidone. One specific surface claimed with both surgical device and tissues.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Soll et al. are set forth above. Specifically, Soll et al. teach that polyvinylpyrrolidone, bovine serum albumin and hyaluronic acid are known in the art to be employed in the protection of corneas prior to surgery and that they all provide some degree of protection.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Soll et al. do not specify the molecular weight of polyvinylpyrrolidone or teach coating both surgical devices and tissues. However, these deficiencies are cured by Lambert.

The teachings of Lambert are set forth above. Specifically, Lambert teach utilizing a hydrophilic coating to produce low coefficient friction on medical devices. Specific medical devices include latex gloves. The molecular weight of polyvinylpyrrolidone taught is from 10^4 to 10^7.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Soll et al. and Lambert and utilize polyvinylpyrrolidone with a molecular weight in the range of 10^4 to 10^7. One of ordinary

skill in the art would have been motivated to utilize this molecular weight of polyvinylpyrrolidone as it is taught as a suitable molecular weight to form a hydrophilic coating and Soll et al. teach that polyvinylpyrrolidone can be utilized to protect corneas prior to surgery.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Soll et al. and Lambert and utilize coatings on both tissues and surgical devices. One of ordinary skill in the art would have been motivated to coat both the tissues and surgical devices prior to corneal surgery as Soll et al. teach coatings comprising bovine serum albumin, hyaluronic acid and polyvinylpyrrolidone can be utilized to coat corneas prior to surgery and Lambert teach coating medical devices including latex gloves which are utilized in virtually every surgery reduce friction during surgery. Therefore, it would have been obvious to one of ordinary skill in the art to utilize coatings in order to protect tissues during surgery. One of ordinary skill in the art would expect that coating both the tissues and the medical devices would have an added effect in protecting the tissues from damage.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 3, 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schechter (US Patent No. 4510145) in view of Chiou (US Patent No. 4564821).

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Specifically claimed polymer is carboxymethylcellulose.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Schacher is directed to a method for controlling the contraction of ophthalmic wounds or incisions (abstract). The composition comprises a smooth muscle relaxant and thickeners are added in order to adjust the viscosity. Suitable viscosity building agents include gums or cellulosic polymer such as carboxymethylcellulose. These polymers are present in an amount from 0.001 to about 1% (column 3, liens 5-20). It is taught that application of the composition can be utilized to control the contraction of ophthalmic wounds or incisions and is particularly useful in preventing the contraction of incision in anterior radial keratotomy (column 1, liens 50-63). The compositions can be applied topically via solution in an ophthalmic vehicle including aqueous solutions (column 2, liens 23-39).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Schacher does not specify the molecular weight of the carboxymethyl cellulose. However, this deficiency is cured by Chiou.

Chiou is directed to ophthalmic compositions. Molecular weight of carboxymethylcellulose taught for being suitable in ophthalmic solutions are from 10,000 to 1,000,000 (column 7, lines 1-19).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Schacher and Chiou and utilize carboxymethylcellulose in ophthalmic solutions to be utilized to control the contraction of ophthalmic wounds or incisions. One of ordinary skill in the art would have been motivated to utilize carboxymethylcellulose as it is a polymer specifically taught by Schacher as being suitable. It would have been obvious to one of ordinary skill in the art to try any of the specifically taught polymers as a person with ordinary skill has good reason to pursue known options within his or her technical grasp. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Schacher and Chiou and utilize carboxymethylcellulose with a molecular weight range from 10,000 to 1,000,000. One of ordinary skill in the art would have been motivated to utilize this weight range as it is a range specifically taught as suitable for ophthalmic solutions. Furthermore, it would

have been obvious to one of ordinary skill in the art to vary the molecular weight in order to optimize the viscosity of the solution. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The rejection of claims 1, 3, and 6-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-14 of U.S. Patent No. 4819617 is **withdrawn** in light of Applicants' argument filed on November 24 2008.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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